



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

8376 02 APR 12 P1:25

APR - 8 2002

Mr. J. Robert Lemon
President
Life Plus International
PO Box 3749
267 E. Main Street
Batesville, Arkansas 72503

Dear Mr. Lemon:

This is in response to your letter of January 28, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product **Heart Formula** uses the claim "...aid in the maintenance of healthy blood pressure." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to your claim about control of blood pressure; that is, a claim that does not establish that the claim is about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure or hypertension, which is a disease.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

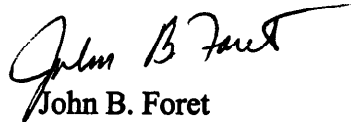
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Page 2 - Mr. J. Robert Lemon

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Foret". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

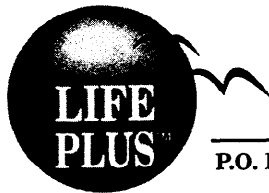
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

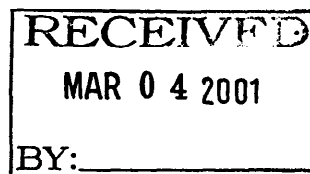
FDA, Dallas District Office, Office of Compliance, HFR-SW140



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P.O. Box 3749 • Batesville, Arkansas 72503 800-572-8446 Bus. FAX 870-698-2379 Order/Apps FAX 1-800-959-2777

January 28, 2002



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. St., SW
Washington, DC 20204


Re: Statement of Nutritional Support Notification

To Whom It May Concern:

I, J. Robert Lemon at LIFE PLUS INTERNATIONAL, 267 E. Main Street, Batesville, Arkansas, am authorized to certify this Notification on behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Life Plus International has substantiation that each statement is truthful and not misleading.

LIFE PLUS INTERNATIONAL

BY:



J. Robert Lemon, President

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 343(r)(6), and implementing Food and Drug Administration regulation, 21 C.F.R. 101.93 (62 Fed. Reg. 49886 (Sept. 23, 1997)), Life Plus International submits this notification on the following nutritional supplements:

Dicalcium Phosphate, Sea Cucumber (*Stichopus japonicus* Selenka) Extract, Hydrolyzed Collagen (Porcine), Norwegian Kelp (*Ascophyllum nodosum* L.) Whole Plant, Zinc Gluconate, Vitamin C (Ascorbic Acid), Magnesium Stearate, Carotenoids (Palm/Carrot Oil), Acerola (*Malpighia punicifolia* L.) Fruit Extract, Natural Vanilla Flavor, Vitamin E (D Alpha Succinate), Vitamin D-3 (Cholecalciferol), and PhytoZyme™ proprietary blend (Bromelain, Papain, Aloe Vera, Alfalfa, Parsley, and vegetable and fruit concentrates from Carrots, Broccoli, Spinach, Cauliflower, Asparagus, Celery, Beet, Chili Pepper, Green Bean, Pea, Sweet Potato, Cucumber, Pumpkin, Snow Pea, Tomato, Zucchini, Lima Beans, Mushroom, Banana, Cantaloupe, Cranberry, Guava, Lemon, Mango, Orange, Papaya, Peach, Pineapple and Grapefruit). The product contains the following claims:

1. Support for collagen in the skin and whole body
2. Helps reduce appearance of fine lines and wrinkles
3. Forever Young tablets contain chondroitin sulfate, collagen-building amino acids, silicon, and other nutrients known for their ability to support healthy collagen levels. These ingredients help the skin to maintain tone, resiliency, and elasticity from within by supporting healthy, youthful skin cells
4. The nutrients support and enhance the body's production of collagen and elastin, the primary structural support system of the skin
5. Many people in clinical studies, as well as consumers, report healthier and more resilient texture of hair and nails, as well as skin, after several months of using this dietary supplement
6. The natural marine extract and other nutrients in Forever Young tablets help promote and maintain healthy levels of collagen and elastin
7. The nutrients provide nutritional support to these structural proteins throughout your entire body
8. Forever Young tablets are especially beneficial for those who live and work in harsh environments that result in increased exposure to free radical attack

Heart Formula is a dietary supplement that contains Magnesium Ascorbate, Bromelain, Betaine HCl, Magnesium Oxide, Trypsin (Porcine), L-Cysteine, Dicalcium Phosphate, DL-Methionine, Vitamin E (D Alpha Succinate), L-Carnitine, Ginger Root Extract, L-Taurine, Carotenoid Complex, Guggul Gum Extract, Choline Bitartrate, Hawthorne Berry Extract, Inositol, Magnesium Stearate, Vitamin B-12 (Cyanocobalamin), Butcher's Broom Rhizome Extract, Lemon Bioflavonoids (Whole Fruit Powder), Rosemary Leaf Extract, Rutin, Turmeric Root Extract, Vitamin B-6 (Pyridoxine), Papain, Manganese Gluconate, Garlic Clove, Magnesium Gluconate, Alpha-Chymotrypsin (Porcine), Niacin (Nicotinic Acid), Vitamin A Acetate, Copper Gluconate, Folic Acid, Vitamin D-3 (Cholecalciferol), Sodium Selenite, Vanadium Pentoxide, and PhytoZyme™ proprietary blend (Bromelain, Papain, Aloe Vera, Alfalfa, Parsley, and vegetable and fruit concentrates from Carrots, Broccoli, Spinach, Cauliflower, Asparagus, Celery, Beet, Chili Pepper, Green Bean, Pea, Sweet Potato, Cucumber, Pumpkin, Snow Pea, Tomato, Zucchini, Lima Beans, Mushroom, Banana, Cantaloupe, Cranberry, Guava, Lemon, Mango, Orange, Papaya, Peach, Pineapple and Grapefruit). The product contains the following claims:

1. Promotes healthy cardiovascular system
2. Heart Formula is designed to support your entire cardiovascular system including the heart, arteries and veins
3. It provides unparalleled support for the heart and circulatory system
4. Heart Formula is a leading edge product designed to assist your circulatory system in supporting all of the cells and organs in your body
5. Scientifically formulated to support the entire cardiovascular system including the heart, veins, and arteries, based upon the latest scientific information
6. Heart Formula's nutrients also aid in the maintenance of healthy blood pressure
7. Antioxidants such as vitamins A,C, E and beta carotene complex may be useful in promoting healthy circulation by protecting LDL cholesterol from free radical attack
8. Heart Formula contains methyl-donating nutrients including choline, betaine and folic acid. These nutrients produce and maintain healthy levels of S-adenosyl methionine which is one of the most active methyl donating compounds. They maintain healthy levels of homocysteine, make the neurotransmitter compounds that are essential to healthy moods and regulate gene expression thus helping to maintain healthy DNA structure and function
9. Includes important herbs for support of healthy circulation such as garlic, hawthorn, ginger, turmeric, Butcher's Broom and rosemary
10. Gugulipid has been shown in modern scientific research to significantly help maintain cholesterol already within normal range and to have potent antioxidant activity
11. Includes specific sulfhydryl-containing amino acids (L-cysteine, D,L-methionine and L-aurine) that help chelate and help the body remove environmental waste
12. The heart muscle contains large amounts of the amino acid L-aurine which specifically supports healthy heart muscle function
13. It is the wide range and specific combination of nutrients that provide such extraordinary support for a healthy cardiovascular system that have made Heart Formula such an outstanding product for so many years
14. Together, Heart Formula, as part of a diet of whole foods that is low in saturated and trans fats, high in fruits, vegetables, fiber, quality protein, essential fats, and clean water, plus an active lifestyle, can help you be heart healthy for life

Joint Formula is a dietary supplement that contains Glucosamine Sulfate (Marine), Magnesium Gluconate, Chondroitin Sulfate (Marine), N-Acetyl D-Glucosamine (Marine), Magnesium Stearate, Hydrolyzed Collagen (Porcine), Manganese Gluconate, Copper Gluconate, Zinc Sulfate, and Phytzyme™ proprietary blend (Bromelain, Papain, Aloe Vera, Alfalfa, Parsley, and vegetable and fruit concentrates from Carrots, Broccoli, Spinach, Cauliflower, Asparagus, Celery, Beet, Chili Pepper, Green Bean, Pea, Sweet Potato, Cucumber, Pumpkin, Snow Pea,